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and Salix Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH IRELAND LIMITED
and SALIX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MSN LABORATORIES PRIVATE LTD.
and MSN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 21-10057

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, “Plaintiffs”) by way of Complaint against Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively, “MSN” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited (“Bausch”) is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. (“Salix”) is a corporation organized and existing under the laws of California, having its principle place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application (“NDA”) No. 208745, which covers Trulance®.

3. Upon information and belief, MSN Laboratories Private Ltd. (“MSN Labs”) is corporation organized and existing under the laws of India, having a place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018 India.

4. Upon information and belief, MSN Pharmaceuticals Inc. (“MSN Pharms”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08837.

5. Upon information and belief, MSN Pharms is a wholly-owned subsidiary of MSN Labs.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 7,041,786 (“the ’786 patent”), 7,799,897 (“the ’897 patent”), 8,637,451 (“the ’451 patent”), 9,610,321 (“the ’321 patent”), 9,616,097 (“the ’097 patent”), 9,919,024 (“the ’024 patent”), 9,925,231 (“the ’231 patent”) and 10,011,637 (“the ’637 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to MSN’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic plecanatide oral tablets, 3 mg (“MSN’s generic plecanatide oral tablets”).

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. Upon information and belief, this court has jurisdiction over MSN Labs. Upon information and belief, MSN Labs is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, MSN Labs directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for MSN's generic plecanatide oral tablets. Upon information and belief, MSN Labs purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, MSN Labs has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. Upon information and belief, this court has jurisdiction over MSN Pharm. Upon information and belief, MSN Pharm is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, MSN Pharm directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for MSN's generic plecanatide oral tablets. Upon information and belief, MSN Pharm purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, MSN Pharm has its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08837. Upon information and belief, MSN

Pharms has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. MSN Labs has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. MSN Labs' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, MSN Labs intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, MSN Labs will engage in marketing of its generic plecanatide oral tablets in New Jersey upon approval of its ANDA.

11. Upon information and belief, MSN Labs and MSN Pharm operate as a single integrated business. Upon information and belief, MSN Labs and MSN Pharm each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

12. MSN Labs and MSN Pharm know or should know that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Trulance®.

13. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

14. Venue is proper against MSN Labs, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

15. Venue is proper against MSN Pharms because it operates a principal place of business in this judicial district.

THE PATENTS IN SUIT

16. The U.S. Patent and Trademark Office (“PTO”) issued the ’786 patent on May 9, 2006. The ’786 patent claims, *inter alia*, peptides and compositions of peptides. Plaintiffs hold all substantial rights in the ’786 patent and have the right to sue for infringement thereof. A copy of the ’786 patent is attached hereto as Exhibit A.

17. The PTO issued the ’897 patent on September 21, 2010. The ’897 patent claims, *inter alia*, peptides and compositions of peptides. Plaintiffs hold all substantial rights in the ’897 patent and have the right to sue for infringement thereof. A copy of the ’897 patent is attached hereto as Exhibit B.

18. The PTO issued the ’451 patent on January 28, 2014. The ’451 patent claims, *inter alia*, methods for stimulating water transport in the gastrointestinal tract. Plaintiffs hold all substantial rights in the ’451 patent and have the right to sue for infringement thereof. A copy of the ’451 patent is attached hereto as Exhibit C.

19. The PTO issued the ’321 patent on April 4, 2017. The ’321 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the ’321 patent and have the right to sue for infringement thereof. A copy of the ’321 patent is attached hereto as Exhibit D.

20. The PTO issued the ’097 patent on April 11, 2017. The ’097 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all

substantial rights in the '097 patent and have the right to sue for infringement thereof. A copy of the '097 patent is attached hereto as Exhibit E.

21. The PTO issued the '024 patent on March 20, 2018. The '024 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the '024 patent and have the right to sue for infringement thereof. A copy of the '024 patent is attached hereto as Exhibit F.

22. The PTO issued the '231 patent on March 27, 2018. The '231 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the '231 patent and have the right to sue for infringement thereof. A copy of the '231 patent is attached hereto as Exhibit G.

23. The PTO issued the '637 patent on July 3, 2018. The '637 patent claims, *inter alia*, purified peptides and processes of purifying peptides. Plaintiffs hold all substantial rights in the '637 patent and have the right to sue for infringement thereof. A copy of the '637 patent is attached hereto as Exhibit H.

24. Salix is the holder of NDA No. 208745 for Trulance[®], which the FDA approved on January 19, 2017. In conjunction with NDA No. 208745, the '786, '897, '451, '321, '097, '024, '231 and '637 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

25. Plecanatide oral tablets, 3mg, are sold in the United States under the trademark Trulance[®].

MSN'S INFRINGING ANDA SUBMISSION

26. Upon information and belief, MSN Labs filed or caused to be filed with the FDA ANDA No. 215780, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

27. Upon information and belief, MSN's ANDA No. 215780 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

28. Plaintiffs received a letter from MSN Labs dated March 15, 2021, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certifications ("MSN's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's Notice Letter was addressed to Salix and Bausch.

29. MSN's Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

30. MSN's Notice Letter states that MSN's ANDA No. 215780 "contains the required bioavailability and/or bioequivalence data from studies on the plecanatide oral tablet drug product," for MSN's generic plecanatide oral tablets.

31. In MSN's Notice Letter, MSN offered confidential access to portions of its ANDA No. 215780, on terms and conditions set forth in the MSN Notice Letter ("the MSN Offer"). MSN required that Plaintiffs accept the MSN Offer before receiving access to MSN's ANDA No. 215780. The MSN Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view MSN's ANDA No. 215780. For example, the MSN Offer contained an improper patent prosecution bar that is contrary, *inter alia*, to the Discovery Confidentiality Order provided at Appendix S to the Local Rules of the District of New Jersey.

The restrictions MSN placed on access to ANDA No. 215780 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access “shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, *as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information*” (emphasis added).

32. Upon information and belief, ANDA No. 215780 seeks approval of MSN’s generic plecanatide oral tablets that are the same, or substantially the same, as Trulance®.

33. Upon information and belief, MSN Labs’ actions related to ANDA No. 215780 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of MSN Pharms.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '786 Patent Under § 271(e)(2)

34. Paragraphs 1-33 are incorporated herein as set forth above.

35. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '786 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval for the commercial marketing of MSN’s generic plecanatide oral tablets before the expiration date of the '786 patent.

36. Upon information and belief, MSN’s generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '786 patent.

37. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN’s generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '786 patent.

38. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '786 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '786 Patent

39. Paragraphs 1-38 are incorporated herein as set forth above.

40. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

42. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '786 patent, including MSN's filing of ANDA No. 215780.

43. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '786 patent.

44. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '786 patent.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the '897 Patent Under § 271(e)(2)

45. Paragraphs 1-44 incorporated herein as set forth above.

46. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '897 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '897 patent.

47. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '897 patent.

48. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '897 patent.

49. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '897 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '897 Patent

50. Paragraphs 1-49 are incorporated herein as set forth above.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

53. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '897 patent, including MSN's filing of ANDA No. 215780.

54. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '897 patent.

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '897 patent.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the '451 Patent Under § 271(e)(2)

56. Paragraphs 1-55 are incorporated herein as set forth above.

57. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '451 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '451 patent.

58. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '451 patent.

59. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '451 patent.

60. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '451 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '451 Patent

61. Paragraphs 1-60 incorporated herein as set forth above.
62. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
63. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.
64. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '451 patent, including MSN's filing of ANDA No. 215780.
65. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '451 patent.
66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '451 patent.

COUNT VII FOR PATENT INFRINGEMENT

Infringement of the '321 Patent Under § 271(e)(2)

67. Paragraphs 1-66 are incorporated herein as set forth above.
68. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '321 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval

for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '321 patent.

69. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '321 patent.

70. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '321 patent.

71. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '321 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '321 Patent

72. Paragraphs 1-71 incorporated herein as set forth above.

73. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

74. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

75. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '321 patent, including MSN's filing of ANDA No. 215780.

76. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '321 patent.

77. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '321 patent.

COUNT IX FOR PATENT INFRINGEMENT

Infringement of the '097 Patent Under § 271(e)(2)

78. Paragraphs 1-77 are incorporated herein as set forth above.

79. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '097 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '097 patent.

80. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '097 patent.

81. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '097 patent.

82. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '097 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '097 Patent

83. Paragraphs 1-82 are incorporated herein as set forth above.
84. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
85. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.
86. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '097 patent, including MSN's filing of ANDA No. 215780.
87. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '097 patent.
88. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '097 patent.

COUNT XI FOR PATENT INFRINGEMENT

Infringement of the '024 Patent Under § 271(e)(2)

89. Paragraphs 1-88 are incorporated herein as set forth above.
90. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '024 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval

for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '024 patent.

91. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '024 patent.

92. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '024 patent.

93. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '024 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '024 Patent

94. Paragraphs 1-93 are incorporated herein as set forth above.

95. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

96. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

97. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '024 patent, including MSN's filing of ANDA No. 215780.

98. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '024 patent.

Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '024 patent.

COUNT XIII FOR PATENT INFRINGEMENT

Infringement of the '231 Patent Under § 271(e)(2)

99. Paragraphs 1-98 are incorporated herein as set forth above.

100. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '231 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '231 patent.

101. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '231 patent.

102. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '231 patent.

103. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '231 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XIV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '231 Patent

104. Paragraphs 1-103 are incorporated herein as set forth above.
105. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
106. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.
107. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '231 patent, including MSN's filing of ANDA No. 215780.
108. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '231 patent.
Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '231 patent.

COUNT XV FOR PATENT INFRINGEMENT

Infringement of the '637 Patent Under § 271(e)(2)

109. Paragraphs 1-108 are incorporated herein as set forth above.
110. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '637 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval

for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '637 patent.

111. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '637 patent.

112. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '637 patent.

113. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '637 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XVI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '637 Patent

114. Paragraphs 1-113 are incorporated herein as set forth above.

115. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

117. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '637 patent, including MSN's filing of ANDA No. 215780.

118. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '637 patent.

Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '637 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against MSN on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '786 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '786 patent;
2. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '897 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '897 patent;
3. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '451 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '451 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '321 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '321 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '097 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '097 patent;

6. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '024 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '024 patent;

7. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '231 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '231 patent;

8. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '637 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '637 patent;

9. Order that the effective date of any approval by the FDA of MSN's generic plecanatide oral tablets be a date that is not earlier than the expiration of the '786 patent, the '897

patent, the '451 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent and the '637 patent, or such later date as the Court may determine;

10. Enjoin MSN from the commercial manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets until expiration of the '786 patent, the '897 patent, the '451 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent and the '637 patent, or such later date as the Court may determine;

11. Enjoin MSN and all persons acting in concert with MSN from seeking, obtaining, or maintaining approval of MSN's ANDA No. 215780 until expiration of the '786 patent, the '897 patent, the '451 patent, the '321 patent, the '097 patent, the '024 patent, the '231 patent and the '637 patent;

12. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

13. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: April 22, 2021
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

J. Brugh Lower

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CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: April 22, 2021
Newark, New Jersey

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